Defendant Exhibit A 14-cr-3024 MWB

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF IOWA

UNITED STATES,

Plaintiff,

v.

QUALITY EGG, LLC, et al.

Defendants.

Case No. 14-cr-03024 (MWB-LTS)

Judge Mark W. Bennett Magistrate Judge Leonard T. Strand

DECLARATION OF CHARLES L. HOFACRE

- I, Charles L. Hofacre, hereby declare, based on personal knowledge of the facts, as follows:
- 1. I am a professor in the College of Veterinary Medicine at the University of Georgia, Department of Population Health.
- 2. I received Bachelor of Science and Master of Science degrees from The Ohio State University, College of Agriculture, Department of Animal Science; Doctor of Veterinary Medicine degree from The Ohio State University, College of Veterinary Medicine; Master of Avian Medicine degree from the University of Georgia, College of Veterinary Medicine, Department of Avian Medicine; and a Ph.D. from the University of Georgia, College of Veterinary Medicine, Department of Medical Microbiology.
- 3. My area of focus is in clinical avian medicine. I have researched organisms that can cause food borne illness in people (salmonella, E.coli, Campylobacter), and I have focused on helping the poultry industry find practical ways to reduce these bacteria. I serve as the Secretary-Treasurer for the American Association of Avian Pathologists and am a member of the American Humane Associations Scientific Advisory Committee. I have published numerous

articles in scholarly journals on the treatment of salmonella and effective methods to control salmonella in facilities that house chickens.

- 4. In addition to my research and teaching pursuits, I regularly advise companies on effective methods to control and reduce the occurrence of salmonella and other bacteria. I have advised companies that produce eggs and handle chickens.
- 5. I was hired by Jack DeCoster to perform consulting work for Quality Egg and others of Mr. DeCoster's companies in September, 2009.
- 6. My recommendations were based on site visits to Quality Egg's facilities in Maine on a quarterly basis from 2009 to 2011 and once to Iowa in February, 2010, and on phone conversations with Jack DeCoster, Peter DeCoster, Duke Goronites, John Glessner, and Tony Wasmann throughout 2009 and 2010.
- 7. Salmonella and Salmonella Enteritidis ("SE") are normal bacteria in the intestine of chickens and can be often found by the egg industry. It is difficult to prevent and treat because it can be part of a healthy, normal chicken's intestines. SE is also a bacteria that can live outside a host for a number of months, if not years.
- 8. The problem that the entire poultry industry faces is that SE is a normal bacteria in the intestines of chicken and causes no health issues for the hen. When an egg is laid, the SE can end up on the exterior shell of the egg or inside the egg.
- 9. The complete elimination of SE from any egg facility is extremely difficult. The correct approach that an egg facility should adopt is to control and manage the presence of SE in the birds' environment, their feed and from the parent flock. This is the approach I take in providing advice to companies.

- 10. Eradication of a normal bacteria in the intestine of a chicken such as S. E. is extremely difficult in a normal poultry farm. Therefore, as Quality Egg was approaching the implementation of the FDA Egg Rule, I recommended that Quality Egg adopt measures to control and manage the presence of SE. This approach is consistent with the Egg Rule.
- 11. I recommended that Quality Egg administer vaccines for protection against SE as well as other diseases. I also recommended that Quality Egg conduct blood tests to ensure that the vaccines had been administered correctly. The University of Iowa conducted these tests called the *pullorum* plate tests. At the time prior to the outbreak almost no layer company in the U. S. gave this number of SE vaccines or tested in this way to insure the vaccine was properly given.
- 12. Before I was hired, Quality Egg tested for SE in the environment. I recommended that these practices continue and that a second party laboratory take the samples and conduct the Iowa State University Veterinary Diagnostic Lab agreed to do this. Quality Egg tests. conducted thousands of environmental tests. I did not review all of these tests, but the ones I did review prior to Spring, 2010 did not register an abnormal amount of SE in the environment. In fact, most of these tests did not detect SE.
- 13. Dr. Maxcy Nolan, a PhD entomologist/pest control expert, designed and helped Quality Egg implement a robust rodent and insect control detection and prevention program. This is an essential part of SE prevention.
- 14. Quality Egg did not start receiving positive environmental results until the Spring of 2010. Before that time, SE positive results were inconsistent and not necessarily suggestive of any significant SE infections.

- 15. In the Spring of 2010, Jack DeCoster and Quality Egg contacted me for assistance in handling the SE environmental positives. Jack wanted advice on how to best treat the SE and control its presence.
- 16. At that time, I recommended the administration of an additional SE vaccine, and I recommended that Quality Egg cease its molting practices, which can increase stress levels and has been well documented to be a significant risk for increased SE in eggs. Even though a significant percentage (if not majority at that time) of egg facilities practiced molting, stopping molting on hens is a significant increase in cost for a producer.

In addition to discontinuing molting I recommended to Mr. DeCoster to stop the use of any rendered animal by product (a less expensive protein source) in his feed because these products can be a significant source of SE.

Also, I suggested in the Spring of 2010 to increase the level of SE testing of farms and their feed mill.

- 17. Quality Egg followed all of my recommendations.
- 18. Despite these efforts to vaccinate and implement the other measures recommended by myself and by Dr. Maxcy Nolan, Quality Egg suffered an SE outbreak. The outbreak was especially unusual because normally SE is not shed into the interior of eggs at the levels that were seen during this outbreak.
- 19. A chicken shedding SE into the interior of an egg is an incredibly rare occurrence. In fact, the leading research in this area is that in a flock of chickens exposed to SE that only 1 in 10,000 eggs contain SE.

- 20. Because there was no evidence that the SE was in the birds or was in the environment and also because it was such an incredibly rare occurrence for SE to be in an egg, I did not recommend that Quality Egg divert its eggs from the market at that time.
- 21. After the outbreak occurred, however, Quality Egg took a number of important steps. They euthanized the birds suspected of carrying SE. They diverted all eggs from the market. They completely cleaned and disinfected and fumigated their barns and facilities. And only after they were confident that no SE was present, after repeated testing, did they bring the egg production facilities back on line.
- 22. One month after the outbreak, I conducted an analysis of the facts to determine just how SE had been shed into the interior of the eggs produced at Quality Egg at such an unprecedented level. Based on my experience and my discussions with other salmonella researchers, I came to the conclusion that the SE outbreak likely occurred due to the administration of an unrelated vaccine designed to prevent Infectious Laryngotracheitis (ILT) and Marek's disease.
- 23. Quality Egg administered a number of vaccines starting in 2009. One of these vaccines was a vaccine to prevent Marek's disease and ILT. The best theory I can put forward is that Quality Egg had vaccinators give the vectored Marek's-ILT vaccine to chicks at 1 day of age and these vaccinators must have missed injecting a significant number of the birds.
- 24. This meant those chicks that did not get the vaccine and were now susceptible to Marek's disease. This disease is caused by a herpes virus that affects the birds' immune system and subsequently causes tumors. When I visited Iowa in February, 2010, I necropsied several hundred hens that had died and many exhibited signs of both ILT and Marek's demonstrating a lack of protection to both diseases. Recommendations were made to improve the vaccination

technique at the hatchery. However, that can only help future flocks since the vaccine must be given at 1 day of age to be effective. In addition to causing tumors the Marek's virus infects and impairs the birds' immune system making them susceptible to secondary infections. The birds not receiving the vaccine now had poorly functioning immune systems. The birds then were exposed to SE most likely from an animal by product meal in the feed. This was confirmed by FDA when they found an SE positive result from inside the lid of the tank holding the meal that Mr. DeCoster had stopped using upon my recommendation. Because they were immune-suppressed, they were not able to clear the SE as a normal hen would do. Instead, the chickens shed SE at a high rate in feces and eggs. The variability in level of SE positive between different flocks could be due to the number of birds missed in the Marek's vaccination.

- 25. I reviewed the record relating to the SE outbreak at Quality Egg and concluded that, for the immune-compromised chickens, the inability to cope with exposure to SE increased the likelihood that those chickens would shed SE into the interior of their eggs.
- 26. The SE outbreak was unlike any other outbreak I had ever read about or studied in the past or even to the present. It was unknown that SE could be put into eggs at such a level with the precautionary measures that were introduced by Quality Egg.
- 27. Before the recall, Quality Egg did not know and had no reason to know that it had shipped eggs that contained SE.
- 28. Peter DeCoster, Jack DeCoster, and others at Quality Egg implemented the recommendations I provided. I always had the sense that Jack and Peter DeCoster were trying hard to prevent SE no matter the cost.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this 30th day of June, 2014, at 12.02

harles L. Hofacy